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09/453,387	12/02/1999	Thea A Wilkins	23070-095600	2583

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EXAMINER

BAUM, STUART F

ART UNIT

PAPER NUMBER

1638

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14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/453,387	WILKINS, THEA A
	Examiner Stuart Baum	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) 4,6,14,16 and 21-26 is/are withdrawn from consideration.

5) Claim(s) ____ is/are allowed.

6) Claim(s) 1-3,5,7-13,15 and 17-20 is/are rejected.

7) Claim(s) ____ is/are objected to.

8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.

4) Interview Summary (PTO-413) Paper No(s). ____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: ____.

Applicant's election with traverse of SEQ ID NO's:1 and 2 in Paper No. 13 is acknowledged. The traversal is on the ground(s) that the sequences can be examined together without causing undue burden. This is not found persuasive because there is undue burden for search and examination and the inventions are distinct as stated in the previous office action.

The requirement is still deemed proper and is therefore made FINAL.

Claim objection, minor informalities

Claims 4, 6, 14, 16, and 21-26 are withdrawn from consideration as drawn to non-elected material i.e., SEQ ID NO's:3-8. Claims 1-3, 5, 7-13, 15, and 17-20 are drawn to the elected sequences and are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 7-13, 15, and 17-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to an isolated *Gossypium hirsutum* cDNA GhMYB1 of SEQ ID NO:1 encoding SEQ ID NO:2 and *Arabidopsis* and tobacco transformation therewith, to obtain tobacco plants with 1) leaf margins and leaf veins bordered by elongated turgid, "waxy-looking" cells, 2) localized increase in density and to some degree increase in length of multicellular trichomes, 3) a notable increase in the basal cell of multicellular trichomes, 4) an increase in the number and density of small, glandular trichomes relative to the untransformed control and 5) a "ballooning" of epidermal cells in an undulating pattern on the surface of the leaf and a proliferation of adventitious roots and an increase in the

distribution, number and length of root hairs, does not reasonably provide enablement for claims broadly drawn to any recombinant expression cassette comprising a promoter sequence operably linked to a heterologous polynucleotide encoding a MYB nucleotide sequence of at least 30 nucleotides in length wherein the expression cassette is used in a method of modulating transcription in a plant and the MYB is expressed in cotton fibers or drawn to plant transformation with the exemplified or non-exemplified genes for obtaining a plant with alterations of root hairs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The Applicant isolated their invention from developing ovules of *Gossypium hirsutum* L. cv Acala SJ-2. The G11 gene was initially used to screen the corresponding cDNA library which yielded the MYB clone GhMYB1 (SEQ ID NO:1) whose sequence was analyzed and compared to 38 other plant MYB protein sequences. Using RT-PCR, the spatial and temporal pattern of GhMYB1 expression was analyzed and determined to be expressed in all tissues tested including developing cotton fibers.

The claims are broadly drawn to a method of modulating transcription in a plant comprising introducing into the plant a recombinant expression cassette comprising a promoter sequence operably linked to a heterologous polynucleotide sequence encoding any MYB polypeptide or a polynucleotide at least about 30 nucleotides in length. The instant specification, however, fails to provide guidance for which amino acids of a MYB polynucleotide can be altered and to which other amino acids, and which amino acids must not be changed, to maintain proper MYB activity of the encoded protein. The specification also fails to provide guidance for

which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional enzyme.

It cannot be predicted by one of skill in the art that nucleic acids that have only 30 nucleotides will have the same activity as full length MYB polynucleotides like SEQ ID NO:1 encoding SEQ ID NO:2. Bowie et al (1990, Science 247:1306-10) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of the protein to fold into unique three-dimensional structures that allows it to function and carry out the instructions of the genome. The cited reference also teaches that the prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex (pg 1306, left column). Bowie et al teach that while it is known that many amino acid substitutions are possible in any given protein, the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three-dimensional structure/function relationship, and these regions can tolerate only conservative substitutions or none at all (pg 1306, right column). The sensitivity of proteins to alterations in even a single amino acid in a sequence is exemplified by Burgess et al (1990, J. Cell Biol. 111:2129-2138), who teach that the replacement of a single lysine residue at position 118 of acidic fibroblast growth factor by glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological activity of the protein.

Payne et al (1999, Development 126:671-682) teach the *MIXTA* myb class gene from *Antirrhinum* and *CotMYBA* a closely related MYB-class gene from cotton was unable to replace the trichome-initiating function of the *Arabidopsis GL1* myb gene. They also teach that

overexpression of *MIXTA* in *Nicotiana tabacum* resulted in the production of supernumerary trichomes whereas overexpression of *MIXTA* in *Arabidopsis* did not have the same effect (page 672, right column, 2nd paragraph) indicating that the functionality of MYB proteins is species specific.

Therefore, given the unpredictability of determining the function of an isolated nucleic acid other than SEQ ID NO:1 on the basis of its nucleotide sequence alone and the unpredictability of altering the phenotype of a plant by transforming it with an isolated nucleic acid that has sequence similarity to a MYB polypeptide or that has at least about 30 nucleotides of a MYB polynucleotide other than SEQ ID NO:1, for the reasons stated above; given the lack of working examples of MYB genes other than SEQ ID NO:1; given the absence of guidance with regard to identification of other MYB genes from the multitude of sequences that would encompass any MYB polypeptide or one comprising any 30 nucleotides of a MYB polynucleotide; given the state of the prior art which does not provide further guidance about MYB genes; and given the breadth of the claims which encompass a multitude of sequences that have not been exemplified, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(f) he did not himself invent the subject matter sought to be patented.

Claims 1, 2, 10-12 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Quattrocchio et al (1998, *The Plant Journal* 13(4):475-488 in IDS).

The claims are drawn to any MYB polypeptide expressed in any plant that modulates transcription.

Quattrocchio et al teach that *an2* is a MYB transcription factor and when overexpressed in *Petunia hybrida* activates the promoter of the dihydroflavonol 4-reductase-A gene (abstract and page 476, right column, 1st paragraph). Quattrocchio et al teach the *an2* gene, which is greater than 30 nucleotides, is operably linked to the 35S CaMV promoter, which is a constitutive promoter expressing in shoots and subcloned into an expression cassette. Given that “activates” is encompassed by the word “modulating”, as stated in claim 1, Quattrocchio et al anticipate the claims.

Claims 1, 2, 9-12, and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Wada et al., (1997, *Science* 277:1113-1116).

The claims are drawn to any MYB polypeptide expressed in any plant that modulates transcription wherein the modulation of transcription results in alteration of root hairs.

Wada et al teach ectopic expression of *CAPRICE* (*CPC*) which encodes a polypeptide with a MYB-like domain, using the 35S CaMV promoter, interfered with the action of GL1 on TTG or GL2 (all are transcription factors involved in root hair formation). The ectopic expression of *CPC* caused altered root hair formation. *CPC* is greater than 30 nucleotides in length and would have been expressed in roots.

Claims 1-3, 7-13, 15, and 17-20 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The reference by Loguercio et al (1999, Mol. Gen. Genet. 261:660-671) discloses Applicant's invention as described above. The Loguercio et al reference discloses additional inventors, L. L. Loguercio and J.-Q. Zhang who by virtue of being included as co-authors on the Loguercio et al paper also contributed to the inventive concept of the instant invention. In addition, the NCBI database discloses SEQ ID NO:1 which was deposited by Wilkins, T.A. and Lu, C.-C. Lu, C. –C. also contributed to the inventive concept. Hence, the Applicant was not the inventor of the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5, 9-12, and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wada et al (1997, Science 277:1113-1116) taken with Wilkins et al (1993, NCBI Accession number L04497).

The claims are drawn to a method of modulating transcription in a plant wherein the modulation of transcription results in alteration of root hairs comprising transforming a plant with a recombinant expression cassette comprising a promoter operably linked to a heterologous polynucleotide sequence encoding a MYB polypeptide wherein the polynucleotide sequence is at least about 30 nucleotides in length and the promoter sequence directs expression in roots.

Wada et al teach a method of modulating transcription in *Arabidopsis* which resulted in ectopic root hair production comprising an expression cassette comprising the *CAPRICE* MYB transcription factor which is at least 30 nucleotides in length, operably linked to the 35S CaMV promoter.

Wada et al do not teach a cotton MYB transcription factor of SEQ ID NO:1 encoding SEQ ID NO:2.

Wilkins et al teach a cotton MYB transcription factor DNA sequence of SEQ ID NO:1, which encodes a polypeptide of SEQ ID NO:2.

Given the recognition of those of ordinary skill in the art of the value of transforming a plant with a MYB transcription factor to modulate transcription and alter root hairs as taught by Wada et al it would have been obvious to modify this method by substituting another MYB sequence, such as the DNA sequence taught by Wilkins et al to produce the same result.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the

Art Unit: 1638

organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the legal analyst, Kim Davis, whose telephone number is (703) 305-3015.

Stuart Baum Ph.D.

March 13, 2002

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600

efm